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(54) Endovascular stent apparatus and method.

(57) A stent for reinforcing a vessel wall is constructed from a single elongated wire. The wire is first bent into a series of tight bends. The wire is then further bent into a sequence of loops that are connected by half hitch junctions and interconnections which are either aligned or spiral around a circumference of the stent. The completed stent forms a cylindrical form which can be expanded from an initial diameter to a larger implanted diameter by application of a radially outward force from a balloon catheter or the like.

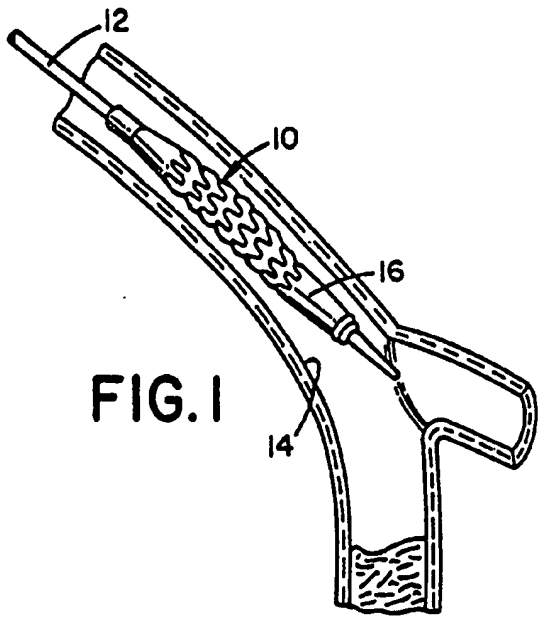

FIG. 1

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Endovascular Stent Apparatus and Method

Technical Field

The present invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel.

Background Art

A type of endoprosthesis device, commonly referred to as a stent, is placed or implanted within a blood vessel for treating stenoses, strictures, or aneurysms in the blood vessel. These devices are implanted within the vascular system to reinforce collapsing, partially occluded, weakened, or abnormally dilated sections of the blood vessel. Stents also have been successfully implanted in the urinary tract or the bileducts to reinforce those body vessels.

One common procedure for implanting the endoprosthesis or stent is to first open the region of the vessel with a balloon catheter and then place the stent in a position that bridges the weakened portion of the vessel.

Prior art patents refer to the construction and design of both the stent as well as the apparatus for positioning the stent within the vessel. One representative patent is U.S. Patent 4,140,126 to Chaudhury which issued February 20, 1979. This patent discloses a technique for positioning an elongated cyclindrical stent at a region of an aneurysm to avoid catastrophic failure of the blood vessel wall. The '126 patent discloses a cylinder that expands to its implanted configuration after insertion with the aid of a catheter.

A second prior art patent to Dotter, U.S. 4,503,569 which issued March 12, 1985 discloses a spring stent which expands to an implanted configuration with a change in temperature. The spring stent is implanted in a coiled orientation and heated to cause the spring to expand.

U.S. Patent 4,733,665 to Palmaz which issued March 29, 1988 discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes a mechanism for mounting and retaining the vascular prosthesis or stent, preferably on an inflatable portion of the catheter. The stent is implanted by positioning it within the blood vessel and monitoring its position on a viewing monitor. Once the stent is properly positioned, the catheter is expanded and the stent separated from the catheter body. The catheter can then be withdrawn from the subject, leaving the stent in place within the blood vessel.

U.S. Patent Application Serial No. 240,000 entitled "Radially Expandable Endoprosthesis and the Like" discloses a generally cylindrical stent formed from a wire that is bent into a series of tight bends and then spirally wound about a cylindrical mandrel to form the stent. If a radially outward force is applied to the stent the sharp bends in the wire tend to straighten and the stent diameter enlarges. One technique for implanting this stent uses a deflated balloon catheter to position the stent within a vessel. Once the stent is properly positioned the balloon is inflated to press the stent against the inner wall linings of the vessel. The balloon is then deflated and withdrawn from the vessel, leaving the stent in place.

Disclosure of the Invention

A stent constructed in accordance with the present invention uses a single elongated wire that is first bent along its length to form a series of tight convolutions. This first fabrication step is similar to the one used in making the stent shown in copending application Serial No. 240,000 mentioned above. This wire is then further formed with the help of a cylindrical mandrel. Instead of spirally winding the wire about the mandrel, a cylindrical form is constructed utilizing a wire interconnection technique which exhibits new and improved expansion characteristics.

The wire is placed over the mandrel in a number of loops which are generally parallel to each other and spaced along the length of the stent by a series of interconnections formed from half hitch junctions. The dimensions of the loops are such that each of such loops has a number of the regularly spaced tight convolutions or bends about its circumference.

The resultant structure has a high degree of flexibility and since each loop forms a generally circular portion of the stent rather than the spiraling portion of the prior art, a more direct and uniform application of expansion forces to the stent occurs.

Use of the invention allows for the omission of one or more stent loops to accommodate branching or crossing vessels within the subject. A backbone is formed by sections which interconnect the half hitch junctions. These sections can either be aligned along the length of the stent or can spiral around the stent's diameter to produce a stent having equal flexibility about the stent circumference.

From the above it is appreciated that one object of the invention is a new and improved stent formed from a series of loops or hoops intercon-

tion 54a and then routed along the length of the mandrel 62 to form the half hitch junction 56.

Slipping the wire underneath an existing transverse section (54a for example) forms a half hitch junction. The process of extending the wire along the mandrel 60 to form a run 54 and routing the wire around the mandrel to form a loop 50 continues until the stent 10 of Figure 2 is completed. Stents of different length and different spacing between loops are contemplated depending upon the specific application for the stent.

The embodiment shown in Figure 2 has a backbone comprising the plurality of transverse runs 54 in an aligned fashion. It is contemplated, however, that the backbone forming runs could be spaced around the circumference of the stent. It is also contemplated that a second support structure could be added to the stent configuration of Figure 2 by looping a single convoluted wire around the loops 50 on an opposite side of the stent 10.

One additional feature of the proposed construction is the use of a variable pitch or distance between adjacent loops. This construction would accommodate for example, the use of the stent wherein side or branch vessels are encountered and would allow unimpeded fluid flow to those side or branching vessels through judicious placement of the stent.

While one application of the stent 10 disclosed in the present application is for implantation within a blood vessel. It is appreciated that the stent 10 has applicability for implantation in other vessels within a subject. It is therefore the intent that the invention include all modifications and alterations from the disclosed design falling within the spirit or scope of the appended claims.

Claims

1. A stent for reinforcing a vessel within a subject comprising a cylindrical support dimensioned to fit within an interior of said vessel constructed from an elongated wire bent to define a series of relatively tightly spaced convolutions or bends, said wire also bent in the form of a plurality of loops spaced along an axial dimension of the stent and connected by a series of half hitch junctions where each of the plurality of loops includes a number of said regularly spaced convolutions around its circumference, said stent being radially expandable from a first outer diameter which fits within said vessel to a second increased diameter which contacts an inner wall surface of said vessel to reinforce said inner wall.

2. The stent of claim 1 wherein the wire is tantalum.

3. The stent of claim 1 wherein an inner diameter of the stent is dimensioned to frictionally engage a non-inflated balloon catheter and be carried by the non-inflated balloon catheter into a blood vessel.

4. The stent of claim 1 wherein the plurality of loops are regularly spaced along the length of the stent and are interconnected by lengths of convoluted wire that are aligned along the length of the stent to form a relatively straight backbone to said stent.

5. The stent of claim 4 wherein gaps are left along the length of the stent to accommodate branches in the vessel so that the stent does not block off fluid flow through the branch.

6. The stent of claim 1 wherein the plurality of loops are regularly spaced along the length of the stent and are interconnected by lengths of convoluted wire that are offset around the diameter of the stent to define a backbone having a relatively wide pitch that spirals about the stent.

7. A method of fabricating a generally cylindrical stent for insertion into a body vessel comprising the steps of:

a) bending an elongated wire in a series of relatively tight convolutions or bends;

b) providing a cylindrical mandrel of a dimension smaller than an inner diameter of the vessel into which the stent is to be inserted;

c) wrapping the elongated wire around the mandrel to form a series of loop segments and interconnecting said loop segments by half hitch junctions and wire portions that connect successive loop segments along an axial dimension of the cylindrical mandrel; and

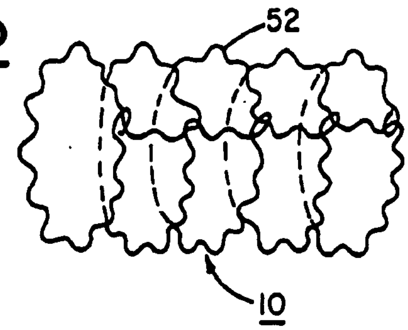
d) removing the elongated wire from the mandrel to define a throughpassage for fluid passage through the stent in a region occupied by the cylindrical mandrel.

8. The method of claim 7 wherein the series of loops are connected by a sequence of wire portions that are radially spaced around the circumference of the stent.

9. The method of claim 7 wherein the series of loops are connected by a sequence of wire portions that align along the length of the stent to form a relatively straight backbone to the stent.

10. The method of claim 7 wherein subsequent to the removal of the stent from the mandrel one or more loops are removed from the stent to accommodate branching vessels and allow unimpeded fluid flow to said branching vessels after the stent is positioned within the vessel.

FIG. 2



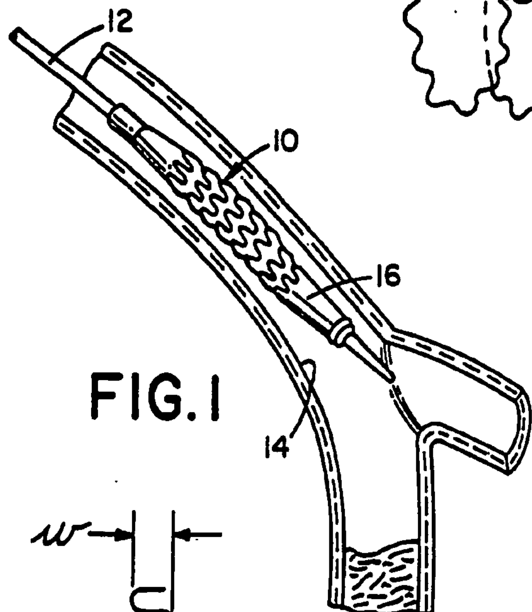


FIG. 1

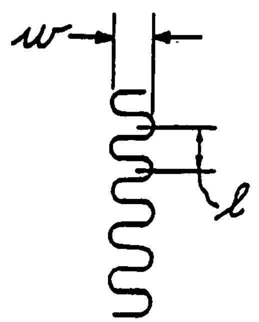


FIG. 4

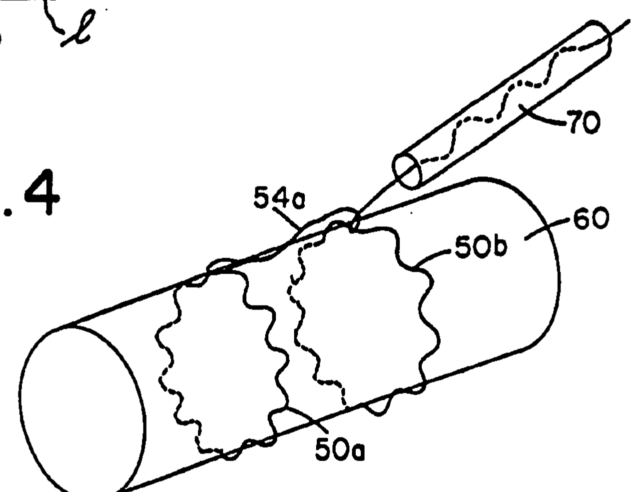


FIG. 3

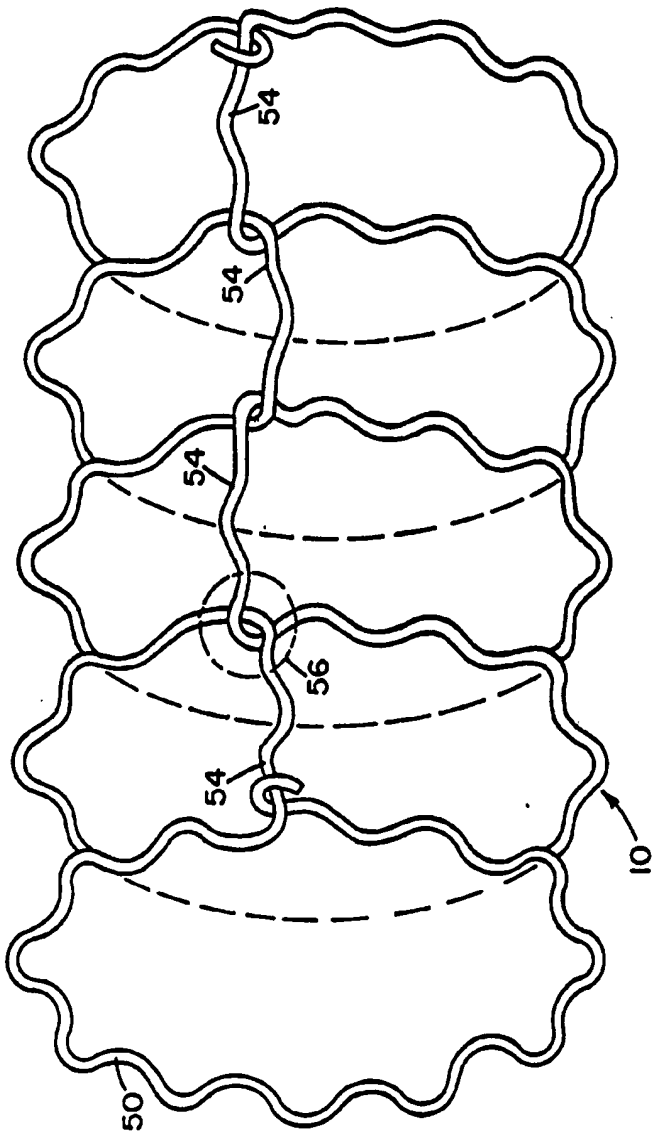


FIG. 2A